

### **REMARKS**

Prior to the present amendment, claims 1-5, 7-38 and 40 were pending. By the present amendment, the subject matter of claims 38 and 40 have been added to claims 1 and 19, respectively. Accordingly, claims 38 and 40 have been cancelled. New claims 41 and 42 have been added and support for these claims can be found, for example, in original claims 1 and 19. Claims 1-5, 7-37 and 41-42 are therefore pending.

### **INFORMATION DISCLOSURE STATEMENT**

In the previous response, a copy of Rezai et al., “Deep Brain Stimulation for Chronic Pain,” in *Surgical Management of Pain*, Chapt. 44, pp. 565-576 (2002) was submitted (such reference having been cited in an IDS filed on 7/23/04). In the previous response, Applicant requested that the Form PTO-1449 included with the previously filed IDS be marked to confirm the Examiner’s consideration of this reference. Such initialed IDS has still not been received and Applicant therefore submits this request again.

### **Rejection of Claims Under 35 U.S.C. 102(e) by Baudino**

Claims 1, 4, 19, 20, 22, 24, 36, 38 and 40 stand rejected as being allegedly anticipated by U.S. Patent No. 6,353,762 to Baudino (“Baudino”). Applicant traverses this rejection.

Baudino describes devices and techniques for selectively affecting and adjusting a volume of neural tissue in the brain and other parts of the nervous system (See Abstract in Certificate of Correction). Baudino is not directed to methods of affecting specific conditions by modulating specific target sites in the brain.

It is true that Baudino mentions chronic pain in passing and it is true that Baudino mentions some of the sites recited in the present claims but it does so in a manner that does not amount to a teaching of affecting chronic pain by stimulating those mentioned sites. Specifically, Baudino refers to chronic pain separately from any sites recited by the present claims such as the anterior limb of the internal capsule, the dorsal medial nucleus of the thalamus, and the anterior nucleus of the thalamus (which are the sites pointed out by the Examiner<sup>1</sup>). Further, these sites are listed among a laundry list of other sites and there is no

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<sup>1</sup> It should be noted that the Examiner also states that Baudino describes the lateral hypothalamus and the ventral pallidum as recited by claim 19. However, this is not what Baudino mentions. Baudino mentions the internal

disclosed connection between any of these sites and any disclosed conditions or disease states that may be treated by stimulation of these sites.

With respect to chronic pain, Baudino only states:

“It is generally desirable to excite particular neural tissue elements of the brain to provide a certain treatment such as treatment of a neurological disorder, the relief of chronic pain, or to control movements.”

Col. 9, lines 21-24. Such a passing comment provides absolutely no target sites for treating chronic pain, let alone detecting a bodily activity associated with chronic pain to adjust a stimulation signal sent to a target site as recited by claims 1 and 19. In fact, such a statement does not provide anything over the art. Neuromodulation of “particular neural tissue elements” to provide “treatment of a [certain] neurological disorder[s]. . . chronic pain or to control movements” has been known. What is not known is the target sites identified by Applicant in claims 1 and 19.

The Examiner relies on a completely separate paragraph of Baudino that describes where the “present invention” can be used to deliver therapy to argue that Baudino teaches treating chronic pain by stimulating these sites. However, the paragraph identifies no specific therapies (i.e. specific conditions are diseases that are treated by modulation of the listed sites). It simply states:

The present invention *may* be used to deliver treatment therapy to any number of sites in the brain. Particular sites within the brain include, for example, the subthalamic nucleus (STN), the peduncular pontine nucleus (PPN), the caudate or putamen, the internal and external pallidum, the cingulum, the anterior limb of the internal capsule, the anterior nucleus (AN), the centremedian (CM), the dorsal medial nucleus and other nuclei of the thalamus, the hippocampus and other structures in the temporal lobe, the hypothalamus and other structures of the diencephalon, the pons, the medulla, the corext, the cerebellum, the lateral geniculate body, and the medial geniculate body. The desired configuration of the electrodes would depend upon the structure of the portion of the brain to be stimulated or infused and the angle of introduction of the deep brain cannula.

Col. 9, line 61 to col. 10, line 9. Thus, these sites are mentioned in conjunction with configuration changes of the device described in Baudino and are certainly not linked to any specific disorders, let alone chronic pain. Baudino couches this list of sites in terms of delivering

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and external pallidum but not specifically the ventral pallidum. Further, Baudino mentions the hypothalamus but not the lateral hypothalamus.

“treatment therapy” but there is no more specificity regarding particular indications or disease states than that.

In fact this lack of any link to chronic pain and the sites mentioned in the above paragraph, can be seen by the statement in Baudino that immediately follows the sentence that mentions chronic pain. Specifically, right after mentioning chronic pain, Baudino states that “often, nearby groups of neurons or axons, e.g., the optic nerve, internal capsule. . . are in special orientations and groupings. It may be advantageous to avoid affecting them. . .” (Col. 9, lines 24-25). This statement is incompatible with the position of the Examiner that Baudino teaches modulating the anterior limb of the internal capsule to treat chronic pain. Clearly, the above-quoted passage states to avoid the internal capsule and says to do so right after a statement that mentions that it may be desirable to provide treatment for chronic pain. This underlines the position that Baudino must be taken in its entirety and bits and pieces cannot be relied upon to support a position that Baudino anticipates the present claims. Just because “chronic pain” and any of the sites recited in the claims are in the same reference does not mean that the reference teaches the subject matter of the recited claims. (See In re Arkley, 455 F.2d 586, 587, 172 USPQ 524 (CCPA 1972) (“the reference ... must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.”); Sandisk Corp. v. Lexar Media, Inc., 91 F. Supp.2d 1327, 1336 (N.D. Calif. 2000) (“Unless all the elements are found in a single piece of prior art in exactly the same situation and united the same way to perform the identical function, there is no anticipation.”).

In addition, as already stated, notwithstanding the above arguments, Baudino does not describe detecting a bodily activity associated with chronic pain and providing a stimulation signal in response to the detected bodily activity to stimulate the target site to affect chronic pain. For at least these reasons, Applicants submit that claims 1 and 19 (and all claims that depend therefrom) are not anticipated by Baudino and Applicant requests withdrawal of this rejection

### **Rejection of Claim 37 Under 35 U.S.C. 102(b) By MacDonald**

Claim 37 stands rejected as being allegedly anticipated by U.S. Patent No. 5,776,170 to MacDonald (“MacDonald”). Applicant traverses this rejection. Claim 37 recites “implanting a stimulator in communication with a pain circuitry target site.” MacDonald is not directed to

implanted stimulators (such as electrodes) but rather surface electrodes. This is clear throughout MacDonald. For example, the Abstract states: “An apparatus for producing analgesia through electrical stimulation is disclosed wherein the apparatus comprises two or more electrodes adapted to supply electrical signals to two or more locations on the surface of a body overlying the central nervous system.” (*emphasis added*). (See also col. 2, lines 21-26). In describing the procedure, MacDonald further states: “[w]e refer to this as Transcutaneous Spinal Electroanalgesia (TSE) and it depends on electrical signal being applied via surface electrodes . . .” (Col. 2, lines 38-40). In describing the TSE stimulator, MacDonald again refers to placing the electrodes on the skin (See col. 3, lines 32-48). Thus, MacDonald does not describe implanting a stimulator in communication with a pain circuitry target site but rather placing electrodes on the surface of the skin. With respect to new claims 41 and 42, MacDonald certainly does not describe implanting any electrodes in the cortical or deep brain regions of the brain as recited by claims 41 and 42. For at least these reasons, Applicant submits that claim 37 is not anticipated by MacDonald and Applicant requests withdrawal of this rejection.

**Rejection of Claims Under 35 U.S.C. 102(b) or 103 by Schiff or Schiff in view of Baudino**

Claims 19, 21, 26-31 and 33-35 stand rejected for being allegedly anticipated by Schiff or in the alternative rendered obvious by Schiff. Claims 1-3, 8-10, 17 and 18 stand rejected for being allegedly rendered obvious by Schiff. Claims 1-36 stand rejected as being allegedly rendered obvious by Baudino in view of Schiff.

Applicant notes that original claims 38 and 40 were not rejected in view of Schiff either alone or in combination with Baudino. The limitations of claims 38 and 40 have been added to claims 1 and 19, respectively. Therefore, without conceding to the propriety of the current rejections, Applicant submits that claims 1 and 19 are allowable in view of Schiff alone or combination with Baudino.

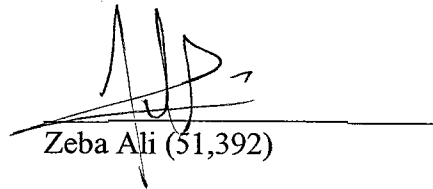
**CONCLUSION**

Applicant respectfully submits that the present application is in condition for allowance. The Examiner is invited to contact Applicant's representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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